



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,965	10/20/2000	Craig M. Thompson	0342/1D516-U	4039

7590

04/25/2003

Darby & Darby
805 Third Avenue
New York, NY 10022-7513

EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/25/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,965

Applicant(s)

THOMPSON ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 3-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1653

Applicant's election without traverse of Invention I, Claims 1-6 in Paper No. Paper #11, filed August 22, 2002 is acknowledged. Upon review of the sequence and word search of the elected invention, it appears that it would not be an undue examination burden on the Examiner to rejoin the polypeptides of Invention II, Claims 7 and 8, and the method of Invention III, Claim 9, with Invention I. Therefore, Claims 1-9 are under examination. Claims 10-13 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions.

The disclosure is objected to because of the following informalities:

The continuing data at page 1 must be updated to reflect that this application is the national stage application of PCT/US99/02940, filed February 8, 1999, which claims priority to U.S. provisional application 60/074,100, filed February 9, 1998.

Additionally, the specification at page 10, line 32 refers to figure 3, which figure does not exist. Reference to figure 3 should be to all of figures 3A-3G. It appears that reference to figures throughout the rest of the specification is correct – see page 28, lines 11, 16, and 27, for example, but Applicants may wish to scan the application for figure reference discrepancies.

The disclosure lacks an abstract.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1653

In Claims 1 and 7, the term "having" can be interpreted as being open or closed language. To clarify, the terms "consisting of" or "comprising" should be used.

In Claims 1 and 7, reference is made to figure 3, which figure does not exist. Reference to figure 3 should be to all of figures 3A-3G.

Claim 2 broadens Claim 1, thus there is no basis in Claim 1 for the nucleic acids that hybridize to it.

Claim 2 refers to "stringent hybridization conditions". Stringency can vary widely in hybridization assays, and therefore the nucleic acids that hybridize to SEQ ID NO: 1 will vary widely. The hybridization parameters desired should be placed into the claim. It is noted that detailed hybridization conditions are set forth at pages 9-10 of the specification; however, these conditions are not stated to be or specifically defined as "stringent" hybridization conditions. Applicants may wish to make Claim 2 an independent claim having definite hybridization conditions.

Claim 8 broadens Claim 7, thus there is no basis in Claim 7 for reference to a fragment of SEQ ID NO: 2.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2 and 8 are being taken to be an independent

Art Unit: 1653

claim because it's dependency on claim 1 is improper under 35 USC 112, second paragraph as noted above.

The specification does not teach or describe nucleic acids that hybridize to SEQ ID NO: 1, or a nucleic acid that hybridizes to SEQ ID NO: 1 having undefined activity, such as histone acetyl transferase activity, for example. Therefore, the limitations of Claim 2 lack written description in the specification. Applicants may wish to amend claim 2 to recite that that nucleic acid encodes a polypeptide that has a defined activity.

The specification does not teach a TBP that binds to *C. albicans* TAF145. For example, in Example 1C at pages 30-31 of the specification, two experiments were performed to determine if *C. albicans* TAF145 could substitute for *S. cerevisiae* TAF145. The conclusion was that *C. albicans* TAF145 could not substitute for *S. cerevisiae* TAF145 because protein surfaces for interactions of *S. cerevisiae* TAF145 with its partners (which is TBP) were not conserved. Indeed, *C. albicans*' TBP was identified by Leng et al. (1998; J. Bacteriol. 180(7):1771-1776) in April of 1998, two months after Applicants' priority date. Therefore, the specification lacks written description of the limitations of Claim 8, drawn to a fragment of *C. albicans* TAF145 (SEQ ID NO: 2) that binds any TBP because, at the time the invention was made, there were no TBP known that could bind to *C. albicans* TAF145 (SEQ ID NO: 2).

While Example 2 prophetically teaches histone acetyl transferase assays using prior art references, it appears that one skilled in the art could identify fragments of *C. albicans* TAF145 (SEQ ID NO: 2) having histone acetyl transferase activity using this teaching.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 9 is drawn to a method for inhibiting fungal transcription in *C. albicans* by contacting a cell with an agent that interferes with the binding of *C. albicans* TAF145 (SEQ ID NO: 2) and TBP.

Art Unit: 1653

As noted above, the specification does not teach a TBP that binds to *C. albicans* TAF-145. For example, in Example 1C at pages 30-31 of the specification, two experiments were performed to determine if *C. albicans* TAF145 could substitute for *S. cerevisiae* TAF145. The conclusion was that *C. albicans* TAF145 could not substitute for *S. cerevisiae* TAF145 because protein surfaces for interactions of *S. cerevisiae* TAF145 with its partners (which is TBP) were not conserved. Indeed, *C. albicans*' TBP was identified by Leng et al. (1998; J. Bacteriol. 180(7):1771-1776) in April of 1998, two months after Applicants' priority date. Therefore, one skilled in the art could not perform the method of Claim 9 because an essential element used in the method of Claim 9 did not exist at the time of filing. Further, an agent that inhibits the interaction of *C. albicans* TAF145 (SEQ ID NO: 2) and any TBP is not taught in the specification.

In *Ex parte Forman* (230 USPQ 546) the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation:

1) Quantity of experimentation necessary: The quantity of experimentation would be undue to a person of ordinary skill in the art because the TBP that binds to *C. albicans* TAF145 would have to be found before even the agent that interferes this binding can be determined. Indeed, Applicants themselves were unable to determine a TBP that binds to *C. albicans* TAF145 such that *C. albicans* TAF145 could be functional in *S. cerevisiae*.

2) Amount of direction or guidance presented. There is no specific guidance to find a TBP in *C. albicans* that binds to *C. albicans* TAF145.

3) Presence or absence of working examples: The examples as set forth in Example 1C demonstrate that the TAF145s of *C. albicans* and *S. cerevisiae* are not interchangeable with *S. cerevisiae* TAF145 binding partners (TBP).

Art Unit: 1653

4) Nature of the invention; 5) State of the prior art; 6) Relative skill of those in the art: The nature of the invention is complex and the prior art recognizes TAFI 45 proteins that bind to TBP that are not derived from *C. albicans*. Those working in the art are highly skilled.

7) Predictability or unpredictability of the art: It is not predictable what TBP will bind to *C. albicans* TAFI 45 protein. It appears that one skilled in the art would simply have to experiment until that TBP is determined.

8) Breadth of the claims: The breadth of the claim would not be unjustified if the TBP that binds to *C. albicans* TAFI 45 were in hand.

For all of these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

Claims 3-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER